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VI
WHITTLESTONE BREAST PUMP
510(K) SUMMARY

Summary Prepared on 25-Aug-00

1. Sponsors Name, Address and Contact Person:

APPLICANT:

Whittlestone, Inc
601A Stone Road
Benicia, CA 94510
Tel.: (877) 608-6455
Fax: (877) 609-6455

CONTACT PERSON:

Bruce McKendry, Vice President
Whittlestone, Inc
601A Stone Road
Benicia, CA 94510
Tel.: (877) 608-6455
Fax: (877) 609-6455

2. Name of the device:

Trade Name:	Whittlestone Breastpump
Usual Name:	Whittlestone Breastpump
Classification Name:	Breast Pump

3. Predicate Devices:

This device is substantially equivalent in basic function and otherwise similar to a number of devices that are in current commercial distribution and use. The following is a partial list of similar devices and their manufacturers/distributors:

Manufacture	Product	510(k) Number
Medela, Inc.	Medela Pump In Style	Unknown
Ameda Egnell	Purely Yours	K973501
Evenflo	Personal Comfort	K983776

4. Device Description:

The Whittlestone Breastpump has been designed for home use. It is a fully enclosed breastmilk expresser that is safe, effective and comfortable (See Illustration 1). Unlike common breast pumps which have hard plastic bell shaped cups, the Whittlestone Breastpump breast cups have a soft foam rubber pad and silicone liner. The liner chamber is connected to the pump housing by soft plastic tubing. Valves on the pump diaphragm automatically admit atmospheric air pressure after each vacuum cycle, causing the liner to rhythmically contract and expand around the nipple area (areola). This action gently massages the breast in a manner similar to the action of a sucking baby.

The breast cups gently stimulate the breasts, compress the milk ducts, and encourage the ejection of milk. The mother can control the vacuum to adjust for her own level of comfort and effectiveness. The vacuum also helps to keep the breast cups in place and removes the milk to the collecting bottles.

Two Expressors are provided so that both breasts can be milked simultaneously, taking advantage of the woman's natural let-down reflex and reducing the time involved in expressing breastmilk.

5. Intended Use:

The Whittlestone Breastpump is an electric powered (diaphragm-type) suction device used to express milk from the breast of lactating women.

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6. Technological Characteristics:

The Whittlestone Breast Pump is substantially equivalent to other powered breast pumps that are in commercial distribution. The following is a chart showing the similarities and differences of the proposed breast pump and the predicate breast pumps:

Parameters	Whittlestone	Medela Pump In Style	Evenflo Personal Comfort	Ameda Egnell Purely Yours
Intended Use	Express Milk	Express Milk	Express Milk	Express Milk
Power Source	AC Power Cord Adapter	1. Rechargeable Battery 2. AC Power Cord Adapter 3. 12 V Car Adapter	1. Battery 2. AC Power Cord Adapter	1. Rechargeable Battery 2. AC Power Cord Adapter 3. 12 V Car Adapter
Suction Levels (measured) Single Pumping Double Pumping	 50-110 mm HG 50-110 mm HG	 80-140 mm HG 80-140 mm HG	 60-80 mm HG 60-80 mm HG	 50-110 mm HG 50-110 mm HG
Suction Cycles (per minute)	43	50	30-60	30-40
Cycling/Suction Controls	Mechanical/Microprocessor	Mechanical	Mechanical	Microprocessor
Single or Double Pumping Option	Single or Double Pumping	Single or Double Pumping	Single or Double Pumping	Single or Double Pumping
Weight lbs.	7 -8	7-8	3-5	5-6
Bacteria Filter or trap to prevent milk back-up into pump	Yes	Yes	Yes	Yes
Uses Standard baby bottles	Yes	Yes	Yes	Yes

7. System Features:

Suction Release:
This mechanism allows the mother to release vacuum pressure when needed during normal operation. It allows quick removal of expresser cups.

Thin-Walled Liner/comfort pad:
The Whittlestone liner is the heart of this product. Made of soft medical grade silicone, the liner gently massages (± 30cmH20 air pressure) the nipple-areola area to encourage milk "letdown" and provide superior milk expression. Covering a soft foam pad the liner and comfort pad, gives a comfortable cushion during expression.

Filter Cap:
The integrated Filter Cap prevents milk or water from entering the pump – an essential feature for maintaining cleanliness and safety.

Compression Massage with Gentle vacuum:
Whittlestone uses gentle vacuum and compression (or pulsation: ± 30cmH20 air pressure) to express milk. The space between the cup and the wall of the liner is injected alternately with positive and negative pressure to gently and rhythmically stimulate – not pull – the nipple area to stimulate milk flow.

8. Non-Clinical Testing:

Performance testing was conducted on the Whittlestone and each of the predicate devices. These test measured the vacuum levels and cycle speeds of the predicate devices compared to the Whittlestone.

9. Conclusion:

Based on the information presented, Whittlestone Inc, has concluded that the proposed Whittlestone Powered Breast Pump is safe and effective for it's intended use and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2001

Whittlestone, Inc.
c/o Richard Janosko, R.A.C.
Regulatory Affairs Consulting
539 Tucker Street
HEALDSBURG CA 95448

Re: K002696
Whittlestone Breastpump
Dated: January 5, 2001
Received: January 8, 2001
Regulatory Class: II
21 CFR §884.5160/Procode: 85 HGX

Dear Mr. Janosko:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number: K002696

Device Name: **Whittlestone Breastpump**

Indications for Use:

Like the predicate devices, the proposed Whittlestone Breastpump is an electric powered (diaphragm-type) suction device used to express milk from the breast of lactating women.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-the-Counter Use** X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002696